

## REMARKS

The Applicants respectfully request reconsideration of the present application in view of the following reasons.

A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. Claims 1-11 and 42-62 remain pending in this application. No claim has been amended.

The Applicants thank Examiner Landsman for the courtesies and assistance extended to the undersigned in the telephonic interviews of October 28 and 29.

The Applicants acknowledge the withdrawal of the rejections under 35 U.S.C. § 103(a).

The Applicants understand that the sole remaining basis for the outstanding rejections is the alleged lack of enablement as set forth originally in the Office Action mailed February 26, 2003. The Applicants rebutted this basis in the response filed February 29, 2004, but they understand that the Examiner continues to maintain the rejections in view of the following assertions: (1) the Applicants have not shown that as much as 25% of a domain can be altered for each of the three domains recited in the claims while maintaining functionality; (2) the specification lacks teaching of which specific residues to change or a function (e.g., ligand binding) against which to determine which residues to change; (3) which G-proteins can be used to make operative fusions; and (4) offered any showing, in particular a Declaration, to demonstrate that a ten-amino acid intracellular loop will be functional.

The Applicants respectfully submit that the Examiner has not set forth a *prima facie* basis for maintaining the outstanding rejections. The Examiner has merely provided certain, specific questions that a person of ordinary skill in the art might face when practicing the invention. But the Examiner has not provided any reason to conclude that answering such questions would require undue experimentation.

The Applicants respectfully point out that the level of skill in the biotechnological arts is quite high, and those of ordinary skill recognize that some experimentation is necessary to perform even routine functions. As M.P.E.P. § 2164, notes, however, “[t]he information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention.... it is not necessary to ‘enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.’” (Quoting *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003).) Here, the Applicants respectfully submit that those of skill in the biotechnological arts understand that nature and function(s) of the materials being coupled to make the claimed fusion proteins. Such persons can practice the invention without undue experimentation.

Furthermore, the Applicants also respectfully draw the Examiner’s attention to M.P.E.P. § 2164.04, which sets forth the requirements for making a *prima facie* rejection: “[a]s stated by the [Court of Customs and Patent Appeals], ‘it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.’” (Quoting *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).) Here, the Applicants respectfully submit that the Examiner has not explained why the points raised in the Office Action mailed April 29, 2004, would require undue experimentation for those having skill in the biotechnological arts. Thus, the Applicants respectfully submit that it is premature to require the Applicants to submit any declaratory materials supporting the present application at this time.

Therefore, the Applicants respectfully submit that the outstanding rejections are improper and respectfully request that the Examiner withdraw the rejections.

The Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.


The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date

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By



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